| L Number | Hits | Search Text | DB | Time stamp |
|---|---|---|---|---|
| 1 | 1 | ("4616656").PN. | USPAT | 2003/07/10 15:36 |
| - | 1 | ("20020013539").PN. | USPAT; US-PGPUB | 2003/07/10 09:52 |
| - | 214 | (600/572).CCLS. | USPAT; US-PGPUB | 2003/07/10 10:50 |
| - | 0 | ((600/572).CCLS.) and breast | USPAT | 2003/07/10 09:53 |
| - | 22637 | breast | USPAT | 2003/07/10 10:03 |
| - | 50 | breast and absorbant | USPAT | 2003/07/10 10:13 |
| - | 6 | absorbant same catheter | USPAT | 2003/07/10 10:16 |
| - | 78 | lactiferous | USPAT | 2003/07/10 13:30 |
| - | 6 | ("4202329" \| "4308859" \| "4346714" \| "4365632" \| "4690825" \| "4731054").PN. | USPAT | 2003/07/10 10:45 |
| - | 4 | 5593384.URPN. | USPAT | 2003/07/10 10:46 |
| - | 1 | (biopsy same breast) and absorbant | USPAT | 2003/07/10 11:17 |
| - | 1038 | biopsy same breast | USPAT | 2003/07/10 12:54 |
| - | 95 | (600/569).CCLS. | USPAT | 2003/07/10 12:54 |
| - | 1 | ("5711309").PN. | USPAT | 2003/07/10 13:31 |
| - | 1 | (("5711309").PN.) and diameter | USPAT | 2003/07/10 15:36 |

# United States Patent [19]

Nicholson et al.

[11] Patent Number: 4,616,656

[45] Date of Patent: Oct. 14, 1986


[54] **SELF-ACTUATING BREAST LESION PROBE AND METHOD OF USING**


[76] Inventors: **James E. Nicholson**, 14 Meadowdam Rd., Lincoln, Mass. 01773; **Roland F. Gatturna**, 169 Kendall St., Walpole, Mass. 02081



[21] Appl. No.: **713,613**

[22] Filed: **Mar. 19, 1985**

[51] **Int. Cl.**[4] ..... **A61B 5/00**

[52] **U.S. Cl.** ..... **128/630**; 128/653

[58] **Field of Search** ..... 128/418, 784–785, 128/774, 630.1, 653, 303.16, 303.17; 604/164–169



[56] **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 2,022,065 | 11/1935 | Wappler | 128/303.17 |
| 2,047,535 | 7/1936 | Wappler | 128/303.17 |
| 3,516,412 | 6/1970 | Ackerman | 128/786 |
| 3,890,977 | 6/1975 | Wilson | 128/785 X |
| 4,103,690 | 8/1978 | Harris | 128/786 X |
| 4,327,722 | 5/1982 | Groshong et al. | 604/169 X |
| 4,349,033 | 9/1982 | Eden | 128/774 |
| 4,401,124 | 8/1983 | Guess et al. | 128/660 |
| 4,405,314 | 9/1983 | Cope | 604/164 X |

OTHER PUBLICATIONS

Porstmann, W. et al., "P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted without Thoracotomy", Amer. Jour. Cardiology, vol. 30, pp. 74–76, Jul. 11, 1972.
44



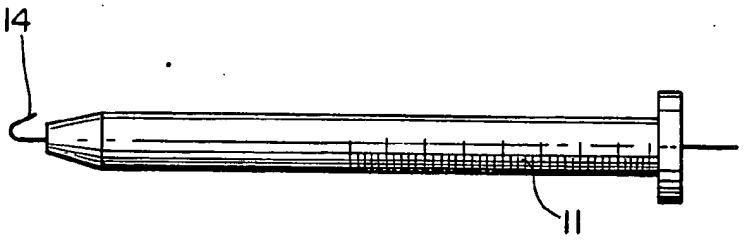
*Primary Examiner*—Kyle L. Howell
*Assistant Examiner*—Francis J. Jaworski
*Attorney, Agent, or Firm*—Morris Kaplan



[57] **ABSTRACT**

A probe sheath and probe wire having a memory hook and soft flexibility are used to locate a small presymptomatic breast lesion, wherein the wire is sheathed within the sheathing cannula and both are inserted into the body tissue and directed to the site of the lesion. Thereafter the wire is extended through the sheath to assume its memory configuration and its location is determined mammographically. If re-positioning is necessary the wire may be retracted into the sheath and then extended and re-anchored after the wire and sheath are directed to a new position. When the probe wire location is acceptable the cannula is removed and the probe wire is left as a marker for surgical excision of the lesion.


**20 Claims, 4 Drawing Figures**



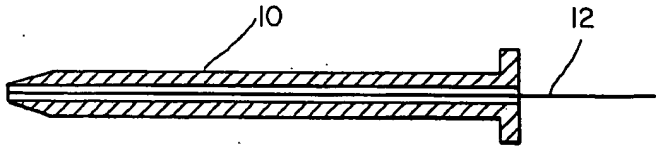



FIG. 1

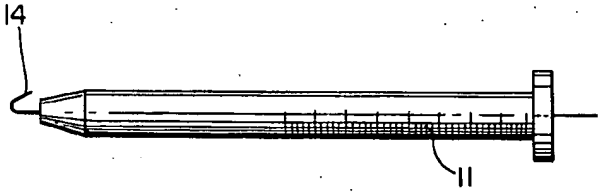



FIG. 2

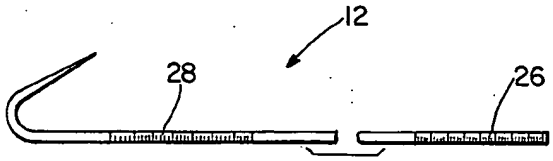



FIG. 3

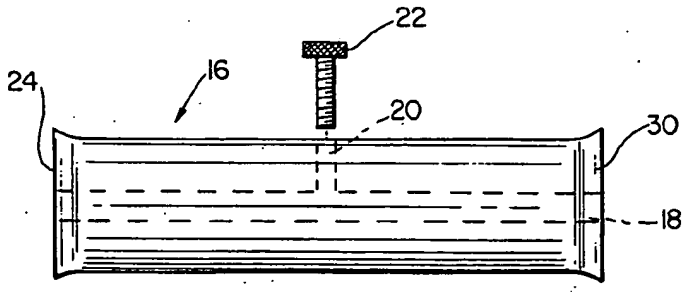



FIG. 4

# SELF-ACTUATING BREAST LESION PROBE AND METHOD OF USING

## TECHNICAL FIELD

The present invention relates to lesion location within the body and is especially adapted to detection and location of presymptomatic, non-palpable lesion within the female breast.

## BACKGROUND OF THE INVENTION

It is known to relay on mammography in conjunction with a needle cannula having a probe wire therein for localization of a presymptomatic, non-palpable breast lesion. In such procedure, a needle cannula having a wire sheathed therein is inserted so that the distal end of the needle is located at about the tissue area of pathological alteration; desirably at less than 2 cm from the lesion. A mammogram is then taken to confirm the probe position. If the probe does not accurately relate to the lesion, then the probe is relocated, or an additional probe may be inserted, and a further mammogram is taken. When the probe location is acceptable, then the cannula needle is removed and the patient transferred to surgery for lesion excision.

Obviously, removal of the lesion with minimal tissue damage will relate to maintenance of the wire's distal end as determined by the final mammographic examination.

In the instance of a straight wire probe, as for instance the Bueno Probe manufactured by Micro-Machining of Claremont, N.H., taping-down or otherwise fixing an extending portion of the wire does not prevent movement of the wire's distal end upon breast movement and expansion after the initial probe procedure.

It is known to use a probe wire having a bend at its distal end whereby when the cannula needle is removed, the bend or hook portion anchors in the tissue. Such known bent or hooked probe wires are for instance the Frank Breast Biopsy Probe manufactured by Randall-Faichney of Avon, Mass., and the Kopans Probe manufactured by Cook, Inc. of Bloomington, Ind. These known, hooked type localization probes have a disadvantage in that once the wire is anchored it can only be removed by resection. Thus, the Kopans Probe would have to be mammographically finally positioned whole its wire element is completely sheathed in the cannula needle. If, after cannula removal, the resultant hook location is unsatisfactory, then another probe means must be inserted.

Hence, the known bent or hooked probe wires have in effect a one-time anchoring use. Further, if more than one wire is relied on, then each anchored wire must be surgically removed with consequent excision of tissue in addition to that of the lesion.

## SUMMARY OF THE INVENTION

The present invention is especially directed to improved means and method for confirming location of a presymptomatic, non-palpable breast lesion by placement and manipulation of a probe comprised of a cannula needle and probe wire therewith.

It is an object of the present invention that the probe wire be of novel construction.

It is a further object of the invention that the novel probe wire comprise inherent anchoring means that inhibit accidental dislodgement of the wire upon ordinary and conventional movement of the body containing the lesion.

It is another object of the invention tha the anchoring means comprise a yieldable memory device that is manually retractable from an anchored location to a sheathed location within the cannula; as for relocation with respect to the lesion.

It is a further object of the invention that the novel probe wire bear graduated scale markings at its distal and proximal end portions.

It is yet another object of the invention that a positive lock means be provided at the proximal end of the probe wire.

It is an object of the invention that the novel and improved cannula needle and wire probe therewith be an uncomplicated combination of simple structural elements, inexpensive and easy to manufacture and simple to manipulate in lesion localization.

For a more fully developed presentation of the invention, and a preferred embodiment thereof, reference is made to the following descriptive matter and attached drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of the probe wire of the invention assembled with a longitudinal section of the cannula and, for clarity of display, in an exaggerated dimensional relationship.

FIG. 2 is a view of the self-actuating hook or memory portion of the probe wire pushed through the cannula as at an anchored location;

FIG. 3 is a view of a preferred embodiment of the probe wire showing graduated scale markings thereon; and

FIG. 4 is an exploded view of a probe wire clamp member.

## DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings which show a preferred embodiment of the invention and wherein like numerals indicate like elements of structure, there is shown in FIG. 1 a conventional probe cannula 10 and an improved probe wire 12 in assembled relationship preparatory to insertion of the unit into the body tissue for lesion location. For purposes of clarity, the dimensional relationship of the cannula and probe wire are exaggerated. In actuality, the wire has a close but easily slidable fit; the wire being for instance approximately 0.015 inches in diameter and the cannula being of 20 gauge. Preferably, the wire is coated, as with a silicone or teflon, for purposes of lubricity and electrical insulation.

As shown in FIG. 1, the probe wire lies straight in its cannula sheathing and as so assembled, the unit is inserted into the body tissue to a location whereat the distal end lies hopefully at about 2 cm from the lesion as previously determined by mammography. The latter is repeated to confirm the accuracy of the probe location. If the desired accuracy is not confirmed, then the probe unit is repositioned and the steps repeated until the desired confirmation is attained.

Following such confirmation, the wire probe end is pushed forward of its sheathed position as illustrated in FIG. 2. Note that the freed wire end 14 has assumed the shape of a relatively small curl or hook whereby the probe wire anchors itself in the tissue at the lesion site.

The probe wire is preferably manufactured of a material having the memory characteristic of such relatively small curl or hook at its freed distal end.

Materials broadly possessing such a memory characteristic and suitable for the inventive purpose are known; as for instance Nitinol, a NiTi alloy produced by Raychem Corp. of Menlo Park, Calif. Such titanium or titanium alloy materials have additional characteristics of being sufficientlyr rigidly whereby to inhibit dislodgement upon subsequent normal and ordinary movement and handling of the body portion in which the lesion is located; are difficult to cut; and will not easily break whereas accidental rupture of the probe wire, as is known to occur with prior art wires, would severely complicate the procedure of lesion excision with minimal damage to the containing tissue. The probe wire could also be formed of a bimetal material that is normally straight but is responsive to body heat for actuation to the hook formation.

In continuation of the localization procedure, a mammographic determination is made to confirm accuracy of the anchored distal end of the probe wire to less than 2 cm from the lesion site.

Assuming that such accuracy is not confirmed, a relocation of the probe wire is desirable in order to effect an optimum surgical result. Obviously, with prior art one-time anchoring usage, such relocation is impossible; either the surgeon proceeds with the less than optimally desirable locater guide or a new round of probe unit insertion/mammographic confirmation is initiated.

However, in the instant case such relocation is possible. The aforedescribed probe wire which is strong enough to prevent accidental dislodgement and breaking, and is tough to cut also has an additional and critical characteristic of being flexibly soft and responsive to manual urging whereby the anchored distal end will release and easily slide from its grasp of tissue and retract into its fully sheathed location within the cannula without further tissue damage.

It is precisely such latter characteristic that most significantly distinguishes the instant probe wire from the prior art. In this connection, it is of interest that the U.S. Pat. Nos. 4,307,723 to Finney and 3,539,034 to Tafeen each disclose a catheter whose distal end possesses a memory characteristic, that U.S. Pat. No. 3,943,932 to Woo discloses an acupuncture needle that may possess a memory characteristic and that U.S. Pat. No. 4,230,123 to Hawkins discloses what is described as a J-wire which is inserted through a cannula for fixing the distal end of said cannula.

Having finally located the probe wire with confirmed accuracy, the cannula is removed. As is known in the art, one may then tape down the proximal portion of the probe wire that extends from the body to thereby further inhibit wire displacement upon subsequent body handling and transportation. However, it is preferred that a more positive means be relied on to both further inhibit wire displacement and to prevent tissue from rising over a section of such extending proximal wire that due to prior manipulation may have become nonsterile.

Such a more positive means may comprise a biased clip type member but a preferred clamp means is illustrated in FIG. 4 wherein member 16 has an aperture 18 axially therethrough and a threaded aperture 20 extending normal to aperture 18 and intersecting same. A threaded clamp-screw 22 operatively associates with aperture 20. The cross-sectional configuration of said clamp means is broadly not material except that, to facilitate handling, the peripheral surface may be ribbed or knurled or, as shown, may be provided with flange portions 30. In use, the clamp means is positioned with the proximal portion of the finally anchored probe wire extending through the axially disposed aperture, the end face 24 of the clamp is brought to bear on the body surface, whereby to prevent body tissue from rising over any of such proximal portion extending from the body, and the screw tightened to thereby fix the parts.

Graduations 26 are provided on the proximal extent of the probe wire. These markings indicate both the depth of the probe wire's distal end when anchored and the depth of the probe unit's distal end when the wire is properly sheathed in the cannula.

Graduations 28 on the extended distal portion of the probe wire are an indication to the surgeon as to relation of incision to the distal end of the wire. Such graduations 28 may extend further along the distal end than is illustrated in FIG. 3.

Graduations 11 on the cannula are provided whereby to indicate the depth of cannula penetration into the body.

Such graduations may be etchings and may be color coded.

The embodiments shown and described are only illustrative of the present invention and are not to be construed as being delimitive thereof; since once apprised of the invention, changes in structure would be readily apparent to one skilled in the art. Hence, the present invention includes all modifications of structure encompassed within the spirit and scope of the following claims.

We claim:

1. A method of locating a lesion, especially a method for locating a presymptomatic, non-palpable breast lesion, comprising the steps of:

(A) mammographically determining the probable location of such lesion;

(B) selecting a probe wire that has at its distal end a relatively small memory hook and a predetermined degree of soft flexibility;

(C) sheathing the probe wire in a needle cannula whereat the wire assumes the straight configuration of the cannula and the distal ends of the wire and cannula are in a predetermined relationship as evidenced by observation of graduated scale markings on the proximal portion of the wire;

(D) maintaining such determined relationship and initially inserting the assembled cannula and probe wire unit into the body tissue to a depth whereat said distal endsd are at about the site of said lesion;

(E) mammographically determining if placement of such distal ends is within a predetermined spacing with regard to the lesion;

(F) repositioning the unit and mammographically determining each aforedescribed placement of said unit until the desired accuracy is achieved;

(G) solely moving the probe wire forwardly to an extent, as determined by further observation of said graduated scale markings, whereby to only free the distal end portion having the memorty hook and whereby the distal end of the probe wire assumes the hook configuration to thereby anchor itself in the tissue;

(H) mammographically determining the spatial relationship of the anchored end of the probe wire to

the lesion with regard to a desired accuracy thereof;

(I) relying on said characteristic of soft flexibility of the probe wire, manually actuating the probe wire to release and easily slide from its anchored position in the tissue to a fully sheathed location within the cannula at said predetermined relationship of the distal ends without injury to the tissue when said desired accuracy has not been effected; and

(J) repositioning the unit as aforedescribed, reanchoring the probe wire as aforedescribed, and repeating the aforedescribed mammographic determinations until the desired accuracy of the spatial relationship of the anchored end of the probe wire to the lesion site is effected.

2. The method of claim 1 comprising the additional steps of:

(K) completely withdrawig and removing the cannula needle; and

(L) fixing the probe wire by clamping a lock means onto the wire and simultaneously in a position whereat one surface of the lock means bears on the body containing the lesion;

whereby, during subsequent transportation and handling of the body, to further inhibit dislodgement of the probe wire and to prevent the body tissue from covering the proximal portion of the probe wire that may have become non-sterile.

3. The method of claim 1 wherein the depth of unit insertion, as described in (D), guided by observation of graduated scale markings on the cannula needle.

4. A method of lesion excision comprising:

locating the lesion by the method of claim 1; and

during surgical removal of the lesion, being guided by observation of graduated scale markings on the distal portion of the anchored probe wire.

5. A probe unit adapted for location of a lesion, and especially for location of a presymptomatic, non-palpable breast lesion, comprising:

(A) a tubular needle cannula adapted for insertion into a body to the site of said lesion;

(B) a probe wire in the form of a simple straight wire closely fitted within, and freely slidable through, said cannula;

(C) said probe wire possessing a memory hook shape at its distal end whereby such end assumes the straight configuration of the cannula when sheathed therein and being dimensioned so as to pierce the body tissue while simultaneously assuming its normal hook configuration when pushed through the cannula to thereby anchor itself in the tissue at the lesion when the probe unit of cannula and probe wire therein has previously been inserted into the body at about the lesion site;

(D) said probe wire possessing the further characteristic of a predetermined degree of soft flexibility whereby said wire is adapted to be manually actuated to release and easily slide from a said anchored location to a fully sheathed disposition within the cannula and without undue destruction of surrounding tissue;

(E) whereby the probe unit may be relocated within the body and the probe wire reanchored within the tissue until a desired accuracy is attained with respect to lesion location; and

(F) the cannula needle being completely withdrawable from the body and operative association with the probe wire.

6. A probe unit as in claim 5 having in combintion therewith a fixing clamp comprised of:

(G) a member having a first aperture axially therethrough and adapted to accommodate the proximal portion of an anchored probe wire when a cannula needle is withdrawn from the body and removed from operative association with the wire;

(H) a threaded aperture disposed generally normal to and intersecting the first aperture;

(I) a clamping screw operatively associated with the threaded aperture; and

(J) a distal face of the member adapted to bear against the body surface through which the anchored probe wire would extend, whereupon the clamp screw would be adapted to lock the proximal portion of said wire and the body surface would be prevented from rising over said extending proximal probe wire portion that may have become non-sterile.

7. A probe unit as in claim 6 wherein the cannula needle has graduated scale markings thereon whereby to determine depth of cannula or probe unit insertion into the body.

8. A probe unit as in claim 6 wherein the probe wire has graduated scale markings on the proximal portion thereof whereby to determine alignment of the distal ends of the assembled cannula and probe wire and whereby to determine the extent to which the probe wire need be pushed through the cannula to only free the memory hook portion for its anchoring function.

9. A probe unit as in claim 6 wherein the probe wire has graduated scale markings on the distal portion thereof whereby during excision of a lesion the surgeon is guided.

10. A probe unit as in claim 5 wherein the cannula needle has graduated scale markings thereon whereby to determine depth of cannula or probe unit insertion into the body.

11. A probe unit as in claim 10 wherein the probe wire has graduated scale markings on the proximal portion thereof whereby to determine alignment of the distal ends of the assembled cannula and probe wire and whereby to determine the extent to which the probe wire need be pushed through the cannula to only free the memory hook portion for its anchoring function.

12. A probe unit as in claim 10 wherein the probe wire has graduated scale markings on the distal portion thereof whereby during excision of a lesion the surgeon is guided.

13. A probe unit as in claim 10 wherein the probe wire is coated with an inert material having predetermined lubricity and electrically insulative values.

14. A probe unit as in claim 5 wherein the probe wire has graduated scale markings on the proximal portion thereof whereby to determine alignment of the distal ends of the assembled cannula and probe wire and whereby to determine the extent to which the probe wire need be pushed through the cannula to only free the memory hook portion for its anchoring function.

15. A probe unit as in claim 14 wherein the probe wire has graduated scale markings on the distal portion thereof whereby during excision of a lesion the surgeon is guided.

16. A probe unit as in claim 14 wherein the probe wire is coated with an inert material having predetermined lubricity and electrically insulative values.

17. A probe unit as in claim 5 wherein the probe wire has graduated scale markings on the distal portion

thereof whereby during excision of a lesion the surgeon is guided.

18. A probe unit as in claim 17 wherein the probe wire is coated with an inert material having predetermined lubricity and electrically insulative values.

19. A probe unit as in claim 5 wherein the probe wire is coated with an inert material having predetermined lubricity and electrically insulative values.

20. A probe wire adapted for use with a cannula needle for location of a lesion, and especially for location of a presymptomatic, non-palpable breast lesion, comprising:

a wire of the type possessing a relatively small memory hook at its distal end thereby being adapted to anchor in tissue at a lesion site when such end is pushed from a sheathing cannula needle that has been inserted into a body containing such lesion;

said wire being adapted to assume a straight configuration within a said cannula and being dimensioned so as to pierce the body tissue while simultaneously assuming its memory hook configuration to effect said anchor;

said wire havig a relatively soft flexibility characteristic whereby said distal end when anchored is adapted to be manually actuated to release and slide from such an anchored position to a sheathed location in said cannula without undue damage to the tissue;

said wire having graduated scale markings at its proximal portion whereby to facilitate location of the wire's distal end with respect to the distal end of a cannula needle to be used therewith and whereby to determine the extent to which the wire need be pushed through a said cannula needle in order to free only the memorty hook portion for its anchoring function; and

said wire having graduated scale markings at its distal portion whereby with the wire properly located and anchored, the markings are adapted to guide a surgeon during excision of a said lesion.

* * * * *

US005623942A

# United States Patent [19]

Pestes et al.

[11] Patent Number: 5,623,942

[45] Date of Patent: Apr. 29, 1997

[54] CELL COLLECTION SWAB

[75] Inventors: Cornelius N. Pestes; Larry L. Pestes, both of Boring, Oreg.

[73] Assignee: MML Diagnostics, Troutdale, Oreg.

[21] Appl. No.: 590,531

[22] Filed: Jan. 24, 1996

[51] Int. Cl.[6] ..... A61B 10/00

[52] U.S. Cl. ..... 128/759; 128/749

[58] Field of Search ..... 128/749–758, 128/759

[56] References Cited

U.S. PATENT DOCUMENTS

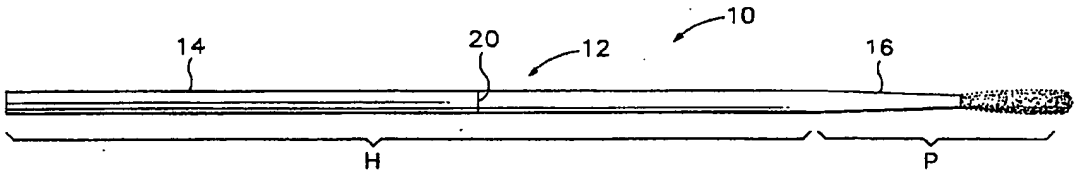
| | | | |
|---|---|---|---|
| 2,839,049 | 6/1958 | MacLean | 128/756 |
| 4,952,204 | 8/1990 | Korteweg | 128/759 |
| 4,981,143 | 1/1991 | Sakita et al. | 128/757 |
| 5,022,408 | 6/1991 | Mohajer | 128/756 |
| 5,031,635 | 7/1991 | Koll | 128/759 |
| 5,084,005 | 1/1992 | Kachigian | 128/756 |
| 5,096,062 | 3/1992 | Burkardt et al. | 128/759 |
| 5,121,752 | 6/1992 | Canna | 128/759 |
| 5,425,377 | 6/1995 | Caillouette | 128/759 |
| 5,522,795 | 6/1996 | Green et al. | 128/759 |

*Primary Examiner*—Sam Rimell
*Assistant Examiner*—Pamela Wingood
*Attorney, Agent, or Firm*—Chernoff, Vilhauer, McClung & Stenzel

[57] ABSTRACT

A swab for collecting cell samples from a male urethra including a unitary elongate shaft having a constant diameter cylindrical handle at one end and a tapered circular cross-sectioned probe at the other end. The shaft is injection molded from a glass filled nylon material with the fiberglass being between 5 and 20 percent by volume and preferably being 10 percent by volume. A fiber tip is mounted at the end of the probe to collect cell specimens.

**7 Claims, 1 Drawing Sheet**



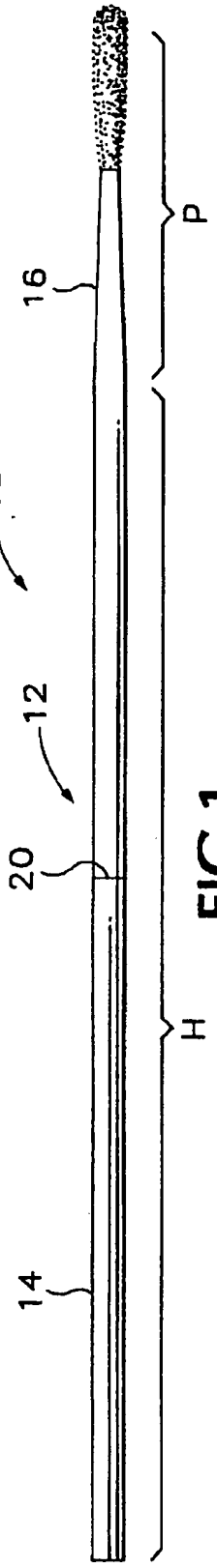



FIG.1

FIG.2
PRIOR ART

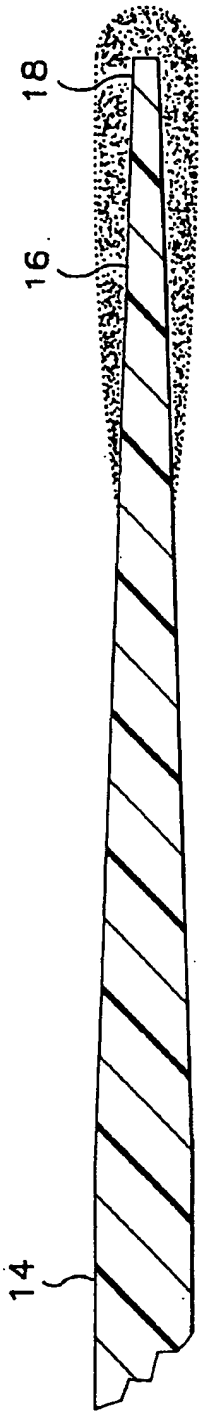



FIG.3

# CELL COLLECTION SWAB

## BACKGROUND AND SUMMARY OF THE INVENTION

This invention relates to a swab for collecting cell samples, and in particular to such a swab for use in collecting samples from the male urethra.

In order to diagnose certain urinary tract or genital diseases or to perform certain types of DNA testing, it is necessary to collect cell samples from the patient's urethra. This process has inherent difficulties with respect to males due to the small size of the urethra and the sensitivity surrounding its opening. First of all the probe end of the swab shaft must be small enough that when covered with the fiber tip that is used to capture cells it will fit comfortably in the urethra. At the same time the handle at the other end of the swab shaft must be sufficiently large to allow it to be firmly gripped. In addition, the swab shaft must be ductile enough so that it will not break and yet be stiff enough that it will not flex excessively during use.

This has been accomplished in the past with a two piece swab shaft. A hollow cylindrical handle has a smaller diameter stainless steel probe inserted into one end. The probe is heat-sealed to the handle. A fiber tip is then attached to the end of the probe. In order to prevent contamination of the collected cells during transportation to the laboratory, a swab of this type is partially inserted into a specimen tube and the protruding portion of the handle is broken off. The handle is scored to provide for breakage at the desired point. In the past this has been accomplished by rotating the handle under a blade.

Because of the cost of the stainless steel probe and the amount of hand assembly work, the prior art swabs are relatively expensive. In addition, carbon in the stainless steel probe may affect the results of DNA testing of samples collected with the swab.

The subject invention overcomes the foregoing problems associated with the prior art swabs by providing a unitary elongate glass filled nylon shaft which has a constant diameter circular cross-sectioned handle at one end and a tapered circular cross-sectioned probe at the other end. The shaft is between 5 and 20 percent fiberglass by volume and preferably is 10 percent fiberglass by volume. A fiber tip is located at the end of the probe to collect cell samples.

Preferably the probe covers approximately 25 percent of the overall length of the shaft and the diameter of the end of the probe is approximately one-third of the diameter of the handle. In the preferred embodiment, the handle has a diameter of approximately 0.100 inches and the end of the probe has a diameter of approximately 0.035 inches. The probe is made by injection molding and a score line is formed in the handle approximately at the midpoint of the shaft, as part of the molding process.

As a result of its shape and material, the subject swab provides similar size, strength and stiffness characteristics as the prior art two piece swabs at far less cost and with an inert probe.

The foregoing and other objectives, features, and advantages of the invention will be more readily understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of a swab embodying the subject invention.



FIG. 2 is a side elevation view of a prior art swab.

FIG. 3 is a detail view of the probe end of the swab of FIG. 1 in cross-section and at an enlarged scale.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1 of the drawings, a swab **10** for collecting cell samples from a male urethra comprises an elongate unitary shaft **12**. The shaft preferably is circular in cross-section and includes a constant diameter handle **14**, designated as "h" in the drawings, and a tapered probe **16**, designated "p" in the drawings. The preferred embodiment of the shaft has an overall length of slightly less than six inches and the probe covers about one quarter of this length. The preferred diameter of the handle is approximately 0.100 inches and the distal extremity **18** of the probe has a diameter of approximately 0.035 inches. While the foregoing configuration is preferred in order to provide an instrument that is properly balanced for ease of use, a handle size that is easy to hold and will not inadvertently break or unnecessarily bend, a considerable amount of dimensional variation is acceptable.

The above described general shape permits injection molding of a one-pieced shaft from a particular material that provides the necessary combination of ductility, stiffness and tip size. As described above and can be seen in FIG. 2 of the drawings, the prior art achieves this combination with a two-piece configuration that is far more costly to manufacture. In addition, by injection molding the shaft, a break line **20** can be formed as part of the molding process rather than having to cut the line as a separate step in the manufacturing process.

The preferred material for the shaft is fiberglass filled nylon. In order to provide sufficient ductility that the shaft will not break in use and still be stiff enough to prevent it from being bent during its intended use, the fiberglass must constitute 5 to 20 percent of the volume of the shaft. Ideally, the fiberglass would constitute 10 percent of the shaft.

After the shaft is constructed, a fiber tip can be applied to its end in the conventional manner to complete the swab.

The terms and expressions which have been employed in the foregoing specification are used therein as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding equivalents of the features shown and described or portions thereof, it being recognized that the scope of the invention is defined and limited only by the claims which follow.

What is claimed is:

1. A swab for collecting cell samples from the urethra of a human penis comprising:
   - (a) an elongate unitary shaft having a handle at one end and a probe at the other end;
   - (b) said handle having a constant diameter, circular cross-section;
   - (c) said probe having a circular cross-section which tapers toward the distal extremity thereof;
   - (d) a fiber tip located at the distal extremity of said probe; wherein
   - (e) said shaft is nylon filled 5 to 20 percent by volume with fiberglass.

2. The swab of claim 1 wherein said shaft is nylon filled 10 percent by volume with fiberglass.

3. The swab of claim 1 wherein said probe covers approximately 25 percent of the overall length of said shaft.

4. The swab of claim 1 wherein said probe has a constant taper with the diameter of the distal extremity being approximately one third of the diameter of the handle.

5. The swab of claim 1 wherein the diameter of said handle is approximately 0.100 inch and the diameter of the distal extremity of said probe is approximately 0.035 inch.

6. The swab of claim 1 wherein said tip covers approximately one half of the length of said probe.

7. The swab of claim 1 wherein said shaft is formed by injection molding and a score line is formed in said handle as a part of the molding process proximate the midpoint of said shaft.

* * * * *